

Appl. No. 10/820,590
Docket No. 9031R
Amdt. dated Nov. 6, 2006
Customer No. 27752

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REMARKS

Claim Status

Claims 1-12 are pending in the present application. No additional claims fee is believed to be due.

Claims 1-3, 5-12 have been amended.

Claim 4 has been cancelled without prejudice.

Claims 13-16 have been withdrawn as a result of an earlier restriction requirement.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Response to Restriction Requirement

Applicants confirm the provisional election with traverse of Group I Claims 1 to 12, tooth whitening composition as discussed with the Examiner by telephone on July 6, 2006. Claims 13-16 are thus withdrawn as non-elected claims.

Traversal of Restriction Requirement

The traversal of the indicated restriction requirement is requested as it is considered improperly made. The Office Action does not show the inventions defined by the groups are independent and distinct. Without a sufficient showing of independence, or relatedness with proper showing of distinctness, the restriction requirement is improper and should be withdrawn.

Applicants respectfully traverse the restriction requirement with respect to the method of manufacture of the tooth whitening composition Claims 13 to 16, which have been withdrawn from consideration as non-elected claims.

Applicants respectfully submit that composition claims (Claims 1 to 12) are so closely interrelated with the method claims (Claims 13-16) in order to preserve unity of invention, should be prosecuted in the same application. The PTO examination would be

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simplified and duplicate searching eliminated by pursuing one as opposed to two or more applications.

§102 Rejection(s)

1) Rejection Under 35 USC §102(e) Over U.S. Patent Application No. 2003/0194382

Claims 1, 3-6, 8, and 11-12 are rejected under 35 USC §102(e) over U.S. Patent Application No. 2003/0194382 (hereinafter "Chang"). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference." Verdegal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), MPEP §2131 (emphasis added). "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989), MPEP §2131. The elements must be arranged as required by the claim. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990). Appellants respectfully submit that the 35 U.S.C. §102(e) rejection is improper because the reference cited by the Examiner does not expressly or inherently teach each and every element set forth in the claims.

The Office Action states that Chang teaches multi-layer patches for teeth whitening. The whitening agents that may be used include hydrogen peroxide... the polymers that may be used to make the adhesive layer or the layer comprising the whitening agent include hydrophilic glass polymers such as polyvinyl pyrrolidone, polyquaternium-11, polyquaternium-39 and polyvinyl pyrrolidone-vinyl acetate copolymer, which have good compatibility with peroxide and are easily soluble in water. The Office Action further states that polyethylene oxide may be used in the compositions of Chang and is not soluble in ethanol but easily soluble in water. The Office Action further states that "another polymer that may be used is polyvinyl alcohol."

Applicants assert that the Office Action fails to point out disclosure of a packaged tooth whitening product comprising a backing layer, a tooth whitening composition comprising a first and second polymer, from about 10% to about 90% water, and a tooth whitening agent wherein the first polymer is polyethylene oxide and the second polymer is polyvinyl alcohol ("PVA"). The Office Action states that Chang discloses "polymers can be used alone or in mixtures..." and "in one of the compositions polyvinyl alcohol comprised 5% of the compositions and the other polymer comprised 12% of the

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compositions...and water comprised 70 of the same composition." First, Applicants assert that Chang does not disclose a mixture of PVA and polyethylene oxide. Second, Applicants assert that Chang is a dry type patch, and therefore, does not teach a packaged tooth whitening product comprising water, as the products in Chang are all dry. (Specification Page 1, Paragraph 0010, Page 6, Paragraph 0063)

Chang discloses a multiple layer dry-type product with three or more layers. One layer is a contact adhesive layer substantially free of peroxide, another layer is an active reservoir layer comprising peroxide as a teeth whitening agent, and the third layer is a backing layer impermeable to water. (Specification Page 2, Paragraph 0011) The Office Action states that Chang discloses the combination of PVA and polyethylene oxide. However, Chang states a list of polymers that can be used in the active material reservoir and a list of polymers that can be used in the adhesive layer; Chang further discloses that in "the active material reservoir layer containing peroxide, all the hydrophilic polymers which may be used in the contact adhesive layer are preferably used." However, Chang does not state that a mixture of the polymers that can be used in the contact adhesive layer can also be used in the active material reservoir layer. Therefore, Applicants assert that Chang does not disclose a mixture of PVA and polyethylene oxide in the active material reservoir layer, the layer that contains peroxide.

Applicants assert that Chang does not disclose a packaged tooth whitening composition comprising from about 10% to about 90% water. The Office Action states that Chang discloses that specific polymers are easily soluble in water and one of the Examples comprises two polymers and 70% water. Applicants assert that the two polymers disclosed in the referenced example were not PVA and polyethylene oxide, and further that the example referenced is not a packaged tooth whitening product, rather it is a solution which becomes a layer in the Chang 3-layered product via conventional extrusion or solvent casting prior to the solution being dried to form a film or layer. (Specification Page 6, Paragraph 0063) Additionally, the fact that the reference discloses that a polymer is water soluble is not the same as disclosing a packaged tooth whitening composition comprising water, as the Chang discloses "it is necessary to select a polymer, which is able to acquire adhesiveness or strengthen its adhesiveness when hydrated by a small quantity of water at a desired place... and the polymer should begin to release a teeth whitening agent upon hydration." Chang concludes that "the inventors have discovered that hydrophilic glass polymers have such properties and thus accomplished

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the present invention by employing hydrophilic glass polymer as a base polymer in a contact adhesion layer.” (Specification Page 3, Paragraph 0028) Therefore, the referenced disclosure in Chang teaches water soluble polymers, not packaged tooth whitening products comprising water, and thus Chang does not teach all elements of the invention as presently claimed.

Applicants further assert that Claims 3-6, 8, and 11-12 are all patentable as they contain all elements of Claim 1.

2) Rejection Under 35 USC §102(e) Over U.S. Patent Application No. 2002/0187181

Claims 1-8, 11-12 are rejected under 35 USC §102(e) over U.S. Patent Application No. 2002/0187181 (hereinafter “Godbey”). Claims 1-8, and 11-12 are rejected under 35 USC §102(e) as being anticipated by U.S. Patent Application No. 2002/0187181 (hereinafter “Godbey”). Appellants respectfully submit that the 35 U.S.C. §102(e) rejection is improper because the reference cited by the Examiner does not expressly or inherently teach each and every element set forth in the claims, as Godbey does not disclose a packaged tooth whitening product comprising a backing layer, and a tooth whitening composition comprising a first and second polymer, from about 10% to about 90% water and a tooth whitening agent wherein the first polymer is a water soluble polymer and the second polymer is polyvinyl alcohol. The Office Action states that Godbey “teaches whitening compositions comprising a first polymer, polyvinyl alcohol, water, a plasticizer and a backing layer.” The Office Action further states that Godbey discloses a “support layer” and that the polyvinyl alcohol used in the examples was “87% hydrolyzed.”

Applicants assert that Godbey fails to disclose a packaged tooth whitening product that has from about 10% to about 90% water. The Office Action states that Godbey discloses a plasticizer of from about 1 to about 50% of the carrier and that the plasticizer can be water. Further the Office Action states that the adhesive composition “may include plasticizers up to 80% and water up to 60%.” Applicants assert that this does not necessarily translate into a packaged product comprising 10 to 90% water, as the carrier layer of the product is prepared by “dissolving at least one polymer and at least one plasticizer in water or other appropriate solvent. The solution thus prepared may be cast into a film, then dried.” (Specification Page 3-4, Paragraph 0028) If the carrier layer is dried, then at least a portion of the water is removed; therefore a water level of about 10%

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to about 90% in a packaged product is not necessarily disclosed. Further the specification states that "using water alone as the plasticizer yields a carrier that is prone to rapid loss of moisture and concomitant change into a glassy or brittle material when exposed to ambient conditions. Hence suitable plasticizers generally include alcohols, mixtures of alcohols, and mixtures of water and alcohols." (Specification Page 3, Paragraph 0026) Therefore, the amount of water that is included as the plasticizer and the amount of water that remains in the product after drying is not disclosed, and thus the amount of water that remains in the packaged product is not disclosed. The Office Action also states that the adhesive composition "may include a polymer in a relative amount of from about 10 to about 60 weight percent of the adhesive composition... and may also include plasticizers up to 80% and water up to 60%." Applicants assert that The Office Action does not point to the disclosure that the adhesive composition further comprises a tooth whitening active, and further assert that water disclosed in the adhesive layer prior to drying does not necessarily disclose a water level of about 10% to about 90% in the packaged product. Therefore, Applicants assert that Godbey does not teach each and every element of the invention as claimed.

§103 Rejections

1) Rejection Under 35 USC §103(a) Over U.S. Patent Application No. 2003/0194382

Claims 2, 7 and 9-10 are rejected under 35 USC §103(a) over U.S. Patent Application No. 2003/0194382. This rejection is traversed. Applicants assert that Chang does not teach all elements of Claim 1 from which Claims 7 and 10-11 depend and Applicants assert that Chang does not teach or suggest all of the claim elements of Claims 7 and 10-11. Therefore, the claimed invention is unobvious and that the rejection should be withdrawn.

To establish a prima facie case of obviousness the Office Action must state that the reference teachings "appear to have suggested the claimed subject matter" In re Wilder, 429 F.2d 447, 166 USPQ 545, 548 (C.C.P.A. 1970). The Office Action must explain why the reference suggests the claimed subject matter, rather than just general aspects of the claimed invention. "It is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification." In re Fine, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

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Chang does not teach or suggest all of the claim elements of Claim 1 and, therefore, does not establish a *prima facie* case of obviousness (see MPEP 2143.03). Chang fails to disclose a packaged tooth whitening product comprising a backing layer, and a tooth whitening composition comprising a first and second polymer, from about 10% to about 90% water and a tooth whitening agent wherein the first polymer is a water soluble polymer and the second polymer is polyvinyl alcohol. The Office Action states that water can comprise about 70% of the composition. Applicants assert that this water level does not remain in the finished product, rather it is the composition prior to the drying step discussed above. Applicants further assert that the product disclosed in Chang is a dry type patch, and therefore, it would not have been obvious to include water, in particular from about 10% to about 90% water, in a dry type patch.

Chang does not teach or suggest all of the claim limitations of Claims 7 and 9-10 and, therefore, does not establish a *prima facie* case of obviousness (see MPEP 2143.03). Specifically, Chang does not teach the combination of two polymers, wherein one polymer is PVA and the second polymer is polyethylene at the average molecular weight of between about 300,000 to about 900,000. The Office Action states that Chang discloses polymers in teeth whitening compositions and "the polymers that are used include polyvinyl alcohol and polyethylene oxides such as Polyox....It is well known the molecular weights of the polyethylene oxides typically range from 100,000 to 8,000,000." The Office Action further states that "polyvinyl alcohols come in several different states ranging from partly hydrolyzed to fully hydrolyzed." The Office Action concludes that "it is well known that the degree of hydrolysis determines the polymer properties such as adhesiveness and viscosity."

As stated in the Office Action, Chang does not specifically disclose the molecular weight of the polyethylene oxides used or that a combination of polyethylene oxides was used. Additionally, Chang does not disclose a combination of polyethylene oxides with different molecular weights. Applicants further assert that Chang does not teach 1) a mixture of polyethylene oxide and PVA, 2) a particular molecular weight of the polyethylene oxide to use in the aforementioned mixture, and 3) a particular hydrolysis of the PVA to use in the aforementioned mixture.

Chang discloses a three layer dry patch. One layer is a contact adhesive layer substantially free of peroxide, another layer is an active reservoir layer comprising peroxide as a teeth whitening agent, and the third layer is a backing layer impermeable to

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water. (Specification Page 2, Paragraph 0011) The Office Action states that Chang discloses the combination of PVA and polyethylen oxide. However, Chang states a list of polymers that can be used in the active material reservoir and a list of polymers that can be used in the adhesive layer; Chang further discloses that in "the active material reservoir layer containing peroxide, all the hydrophilic polymers which may be used in the contact adhesive layer are preferably used." However, Chang does not state that a mixture of the polymers that can be used in the contact adhesive layer can also be used in the active material reservoir layer. Therefore, Applicants assert that Chang does not disclose a mixture of PVA and polyethylene oxide in the active material reservoir layer, the layer that contains peroxide.

The Office Action states that Chang discloses polyethylene oxide, and sites the molecular weights available for any polyethylene oxide having a range from 100,000 to 8,000,000 (as stated by Dow Chemicals). However, neither reference cited teaches the range as claimed, or the combination of PVA with polyethylene oxide having a range between about 300,000 and about 900,000. The Office Action does not cite any reference which would suggest that choosing a particular molecular weight of polyethylene oxide when combining with PVA to form a tooth whitening product would result in any benefit. Therefore, there exists no motivation to modify the broad range disclosed by Dow Chemicals to the claimed range when combining polyethylene oxide with PVA.

Applicants further assert that the Office Action fails to cite a reference which teaches the claimed hydrolysis for PVA. Chang does not disclose a hydrolysis level for PVA, and no reference cited by the Examiner in the Office Action would motivate a person skilled in the art to choose a particular hydrolysis level for PVA when combining with another polymer.

2) Rejection Under 35 USC §103(a) Over U.S. Patent Application No. 2002/0187181 in view of U.S. Patent Application No. 2002/0187111.

Claims 1-12 are rejected under 35 USC §103(a) over U.S. Patent Application No. 2002/0187181 (hereinafter "Godbey") in view of U.S. Patent Application No. 2002/0187111 (hereinafter "Xu"). Applicants assert that Godbey in view of Xu does not teach all elements of Claim 1-12. Applicants assert that Godbey fails to disclose a

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packaged tooth whitening product that has from about 10% to about 90% water. Applicants assert that a disclosure of a plasticizer added at 1-50%, does not necessarily translate into a packaged product comprising about 10% to about 90% water, as the carrier layer of the product is prepared by "dissolving at least one polymer and at least one plasticizer in water or other appropriate solvent. The solution thus prepared may be cast into a film, then dried." (Specification Page 3-4, Paragraph 0028) If the carrier layer is dried, then at least a portion of the water is removed; therefore a water level of about 10% to about 90% in a packaged product is not necessarily disclosed. Further the specification states that "using water alone as the plasticizer yields a carrier that is prone to rapid loss of moisture and concomitant change into a glassy or brittle material when exposed to ambient conditions. Hence suitable plasticizers generally include alcohols, mixtures of alcohols, and mixtures of water and alcohols." (Specification Page 3, Paragraph 0026) Therefore, Godbey teaches away from the inclusion of only water as the plasticizer. The Office Action also states that the adhesive composition "may include a polymer in a relative amount of from about 10 to about 60 weight percent of the adhesive composition... and may also include plasticizers up to 80% and water up to 60%." Applicants assert that the Office Action does not point to the disclosure that the adhesive composition further comprises a tooth whitening active and a backing layer or suggests the benefit of mixing the adhesive composition with the tooth whitening active and applying it to a backing layer.

Specifically referring to the elements of Claims 2-3, 5-12, Applicants assert that Godbey in view of Xu does not teach these elements. As stated in the Office Action Godbey does not teach mixtures and the molecular weight of polyethylene oxide. The Office Action cites Xu, stating "Xu teach(es) whitening strips comprising polyethylene oxide...the properties of the films are varied by varying film thickness and using a mixture of different molecular weight polyethylene oxide polymers (100,000 – 1,500,000 Daltons)." However, the Office Action recognizes that Xu does not teach a second polymer such as polyvinyl alcohol. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to have used the polyethylene oxides of different molecular weights and mixtures in the compositions of the primary reference motivated by the desire to make an adhesive layer that provides a good balance of cohesive strength, water-solubility and the desired rate of release of the whitening agent, as disclosed by the secondary reference." Applicants assert that no motivation to modify the references in such a manner exists, and further that this is improper hindsight

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reconstruction. A general disclosure of molecular weights does not lead a person skilled in the art to choose a particular molecular weight of polyethylene oxide when combining with polyvinyl alcohol in a tooth whitening product. Further, Xu fails to disclose combining such a polyethylene oxide with a second polymer such as PVA. Therefore, Applicants assert that the invention as claimed would not have been obvious.

Obvious-Type Double Patenting

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/936,756.

Applicants assert that the claim scope of the two applications is not the same, however in the interest of furthering prosecution Applicants are prepared to file a terminal disclaimer upon notice of allowable subject matter.

Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections. Early and favorable action in the case is respectfully requested.

Respectfully submitted,

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